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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,529	08/15/2003	Joseph P. Errico	SPINE 3.0-437 P P P P C VI	3170
530 7590 06/13/2008 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 06/13/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/642,529	Applicant(s) ERRICO ET AL.	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-30,41,43 and 47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-30,41,43 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the limitation that only the perimeter of the wire mesh is disposed in the groove such that only the perimeter is in contact with a coating was not described in the written disclosure. According to the specification (paragraphs 180,181) it is noted that the coating is used to secure the mesh to the baseplates, but it does not exclude placing the coating over the entire surface or the mesh being devoid of the coating. Thus, it is not seen where the disclosure states the coating is in an isolated area (i.e. the groove only) and not present anywhere else on the mesh.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-30,41,43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's disclosure describes the coating

as burying the mesh to secure it to the baseplate, paragraph 179. Applicant's specification also states the coating is on the mesh, paragraph 181. Thus, there is no support for the coating to be only on the mesh in the groove and not on the central portion of the mesh. It is not evident where the disclosure states that the other portions do not also have the coating disposed thereon.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 21-24,26-30,41,43,47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner (5370697) in view of Hedman et al. (4759769) and Krebs et al. (5926685) and Kuras et al. (6162252). Baumgartner shows (Fig. 5) a vertebral contact element **44** on the exterior surfaces having a resting shape of a dome convexly extending from an orthopedic device **2**. Baumgartner discloses the contact element is a wire mesh (col. 3, lines 54-57) that is porous. The mesh is fully capable of having a convexity depth or footprint approximating the depth of a concave surface in a vertebrae. However, Baumgartner fails to disclose the outer surface having a groove or an osteoconductive feature, such as a coating for attaching the exterior contact element and the coating only contacting the mesh. Hedman et al. teach (Figs. 1,2) that a recess or groove **34,52** is used in the plate surfaces to secure or retain the resilient spring elements therein, col. 3, lines 24-26. Krebs et al. teach that a coating or binder is used to secure a metal mesh to the surface of the implant, col. 2, lines 14,17,36-39. Kuras et

al. teach a perimeter and groove **56** that has a coating **96** only disposed with its region. It would have been obvious to one of ordinary skill in the art to incorporate a groove in the exterior surface to retain a compressible member therein as taught by Hedman et al. and utilize a coating or binder held in a groove as taught by Krebs et al. and Kuras et al. in the implant of Baumgartner such that together, the incorporation of these exterior surface modifications secure the mesh to the implant stronger and eliminates any sliding or dislodgement of the mesh from the baseplates. The coating being disposed only in the groove is advantageous such that it does not “slide” off in its liquid form.

Claim 21,25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner (5370697) in view of Hedman et al. (4759769) and Koch et al. (4969907) and Kuras et al. ‘252. Baumgartner in view of Hedman is explained supra. However, Baumgartner as modified by Hedman fail to disclose a coating such as plasma spray for securing a metal to an implant surface. Koch et al. teach an implant **1** body’s exterior surface has a coating **5** to secure a contact element **6**. Koch also teaches that the coating secures the implant to the contact element and can be a plasma spray, col. 2, lines 3-6,44-48. However, Baumgartner as modified by Hedman and Koch fail to disclose the coating only contacting the perimeter of the mesh. Kuras et al. is explained supra. It would have been obvious to one of ordinary skill in the art to incorporate a groove in the exterior surface to retain a compressible member therein as taught by Hedman et al. and utilize a coating or binder as taught by Krebs et al. and only in a groove region as taught by Kuras et al. in the implant of Baumgartner such that together, the incorporation of these exterior surface modifications secure the mesh to

the implant stronger and eliminates any sliding or dislodgement of the mesh and coating from the baseplates.

Response to Arguments

Applicant's arguments filed 2/29/08 have been fully considered but they are not persuasive. The Applicant argues that there is no recitation of the mesh not having the central portion including a coating. However, this is with respect to an interpretation of which the Examiner interprets the limitation of claim 21 where it recites "a coating disposed within a groove and being in contact with only a perimeter of the vertebral contact element" to mean solely in the groove and nowhere else. Thus it can be interpreted to mean there is no coating on the mesh other than the perimeter in the groove. The disclosure did not limit the coating to be used this way.

Applicant also argues the rejection has not established a prima facie case of obviousness. In response to applicant's argument that Baumgartner's vertebral body contact element is used for a different purpose, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Since there is a gap between the mesh and plate it is compressible and capable of deflection. Thus one would look to ways to retain such structure that compresses, such as springs. Hedman provides a clear teaching of how to retain a compressible member in a groove. Applicant additionally argues that the only portion of the mesh in the groove is the

perimeter and Baumgartner would not. The Examiner is not persuaded since there is clearly a gap to form a perimeter region that lies against or would be attached to the plate. Applicant additionally concludes that the teachings of Kuras and Koch would not be obvious since the other modification is not obvious. Thus, since the claims rejected over either Koch and Kuras have not been disputed to meet the claim limitations for what these references were applied, the coating and its application, these rejections are maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738